

Biedermann, et al.
USSN 10/040,703
Page 6 of 8

REMARKS

In view of the above amendment claims 12-24 are pending.

Applicants appreciate the courteous interview extended by Examiner Bonderer June 9, 2004 to Applicants' representatives. During the interview, a prototype of the present invention was demonstrated along with a commercial product made according to the Metz-Stavenhagen patent (US 6,074,391). Also, a copy of literature for the "xia spinal system" which contains information about the commercial product made according to the Metz-Stavenhagen patent was provided to the Examiner. The substance of the remarks made by Applicants' representatives will be included in the discussion below.

Claim 21 is submitted in independent form in view of the indication of allowability in the Office Action dated November 7, 2003. Claim 12 is amended to more particularly point out and distinctly claim the subject matter regarded as invention. No new matter is added. Amended claim 12 has no change in scope.

New claims 23 and 24 are provided in order to claim the present invention in different ways to afford better protection for the scope of the present disclosure.

The claims are rejected over Metz-Stavenhagen, et al. (Metz; U.S. 6,074,391). The Examiner has concluded that cage 106 of Metz is the head of the screw of the Metz anchoring element. Applicants' strongly disagree.

Biedermann, et al.
USSN 10/040,703
Page 7 of 8

The present invention requires the spherical head to of the bone screw to be a separate part from the shank having the threaded section. Thus, the shank can be inserted into the bone tissue prior to placement of the spherical head on the shank. In practice the spherical head and receiving section would be preassembled and positioned onto the shank after the shank has been placed in the bone tissue and adjusted to the desired length. The ability to insert the threaded shank first, without the head, can provide better visibility of the surrounding area and the place where the screw is to be inserted, and handling can be easier. Also, the separate head can be removed after it is put onto the shank, allowing for the possibility that adjustments can be made several times, when required, for example, adjustment of the length of the screw shaft or turning the screw an additional turn or portion thereof, etc.

If the cage 106 is considered to be the separate head in Metz-Stavenagen, then the head is not spherical. The **integral** head of the bone screw of Metz-Stavenagen is spherical, but **fails** to be a **separate** part from the shank of the screw.

Further, the structure of Metz-Stavenagen fails to provide the benefits of the presently claimed structure. As shown in FIG. 11 of Metz-Stavenagen, the top of cage 106 is larger than the opening in the opening of receiving part 108 through which it must be inserted. Further, the head 102 of the integral bone screw is larger than the opening in cage 106 which holds the bone screw. Although there is a slot in the cage, as demonstrated during the interview, due to the steel cage it is difficult to compress the cage to insert it into the receiving part. Then, if one is able to do so, the spherical head of the bone screw somehow must be forced into the cage. On the other hand, if the head is placed in the cage first, then it is impossible to insert into the receiving part 108. All this is very impractical to accomplish during an operation, especially after the screw is inserted first into bone tissue, which may be fragile. Thus, the commercial product is pre-assembled, as with the many prior art anchoring elements of this type.

Biedermann, et al.
USSN 10/040,703
Page 8 of 8

Thus, the structure described by Metz-Stavenagen cannot provide the benefits of the presently claimed anchoring element having a bone screw in separate parts.

Thus, it is clear that Metz-Stavenagen fails to anticipate the present invention. Further, it is not seen how the present invention would have been obvious to one of ordinary skill in the art in view of Metz-Stavenagen.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,

Date: June 24, 2004

By: 

George W. Neuner
Reg. No. 26,964
Edwards & Angell, LLP
P.O. Box 9169
Boston, MA 02209
(617) 439- 4444

Customer No. 21874

DOS2_447837.1